IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. MEDTRONIC VASCULAR, INC. BOSTON SCIENTIFIC CORPORATION, and SCIMED LIFE SYSTEMS, INC., Defendants.	Case No. 97-550-SLR (Consolidated)
BOSTON SCIENTIFIC CORPORATION, and SCIMED LIFE SYSTEMS, INC. Plaintiffs, v. ETHICON, INC., CORDIS CORPORATION, and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO. Defendants.	Case No. 98-19-SLR

BSC'S OPENING BRIEF IN SUPPORT OF ITS
RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW
AND, IN THE ALTERNATIVE, FOR A NEW TRIAL

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April 19, 2005

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Defendants Boston Scientific Corporation and Boston Scientific Scimed, Inc. (formerly Scimed Life Systems, Inc.) (collectively "BSC") respectfully submit this opening brief in support of their renewed motion for judgment as a matter of law (JMOL) pursuant to Fed. R. Civ. P. 50(b),[1] and, in the alternative, their motion for a new trial pursuant to Fed. R. Civ. P. 59(a).

SUMMARY OF ARGUMENT

A. JMOL of Noninfringement

The Court should grant BSC JMOL of noninfringement of claim 23 of the '762 patent because Cordis's evidence of infringement was insufficient as a matter of law. The claim requires the "wall" defined by the "wall surface" of the "tubular member," not the wall defined by the "wall surface" of the individual struts or starting material, to have a "substantially uniform thickness." Cordis's evidence of infringement was limited to proof that the individual struts and starting material of the NIR stent are uniformly thick. That evidence cannot legally support the verdict because it is inconsistent with each of: (1) the claim language; (2) the Federal Circuit's mandate on how to measure the thickness of the "wall surface"; (3) this Court's construction of the "substantially uniform thickness" limitation; and (4) the public record in the contemporaneous reexamination prosecution history of what Cordis meant by the wall thickness of a "tubular member" with twisted struts. Cordis also did not challenge or respond to BSC's evidence that the thickness of the "wall" of the "tubular member" of the NIR stent is not "substantially uniform" because of the thickness variations created by the protruding U-loops, which exceed the 100% outer limit of the Court's claim construction.

[1] BSC timely moved at trial for judgment as a matter of law of noninfringement and obviousness pursuant to Fed. R. Civ. P. 50(a) . Tr. 838:5-9; 1197:23-98:11.

B. New Infringement Trial

In the alternative, the Court should grant BSC a new trial on the "substantially uniform thickness" infringement issue for three reasons.

First, it was prejudicial error to instruct the jury during jury deliberations without keeping a written record of the instruction, and to instruct them to the effect that the "wall surface" limitation was not in dispute, when the correct identification of the "wall surface" was both intensely disputed and critical to whether the "substantially uniform thickness" limitation was met.

Second, it was reversible error for Cordis to introduce and rely on undesignated deposition testimony that was not admitted into evidence to mislead the jury into believing that BSC admitted the "wall surface" of the "tubular member" had a "substantially uniform thickness," when the testimony and related exhibits actually related only to the thickness of individual struts.

Third, the infringement verdict is against the weight of the evidence for the reasons stated in BSC's JMOL motion.

C. JMOL of Invalidity

The Court should grant BSC JMOL of invalidity of claim 23 for obviousness because BSC's evidence that the claimed device is almost identical to the prior art Ersek device and that the very minor differences are so trivial that the claimed device would have been obvious was sufficient to meet BSC's clear and convincing burden and was unchallenged by Cordis. Cordis's evidence on validity was limited to irrelevant proof that Dr. Palmaz's combination of a stent on a balloon and his method of intraluminally delivering and expanding a stent on a balloon—neither of which are claimed in claim 23—would not have been obvious in view of the invasive surgical method disclosed in the Ersek patent.

D. New Obviousness Trial

In the alternative, the Court should grant BSC a new trial on the obviousness issue for four reasons.

First, it was prejudicial error to allow Cordis to introduce evidence about the stent-balloon combination and intraluminal delivery method covered by other '762 patent claims that were not in suit, while simultaneously precluding BSC's witnesses from responding to this evidence by describing and contrasting those other claims with the device claim 23 that was in suit.

Second, it was prejudicial error to allow Cordis to argue that the commercial success of all stents in the market was attributable to the structural limitations of claim 23, while simultaneously precluding BSC from responding to that argument with dramatic evidence that other structural features, particularly flexibility, were far more important than any of the structural features of claim 23 to the success of stents on the market, as demonstrated by the "Project Olive" evidence that Cordis was prepared to pay $335 million for the flexible NIR stent—more than three times as much as its $100 million investment in the Palmaz-Schatz stent.

Third, it was prejudicial error to allow Cordis (under the guise of purported impeachment) to use and rely on misleading characterizations of the testimony of Dr. Ersek and Dr. Heuser—who were not witnesses at the trial, but who gave testimony at a different trial—to argue that the prior art Ersek device was different from claim 23 because Dr. Ersek and Dr. Heuser had admitted that it was like a "stapler," when both of them testified it was not.

Fourth, the nonobviousness verdict is against the weight of the evidence for the reasons stated in BSC's JMOL motion.

ARGUMENT

I. The Court Should Grant BSC Judgment As a Matter of Law of Noninfringement Because There Is No Legally Sufficient Evidence That the "Wall" Defined By the "Wall Surface" of the "Tubular Member" of the NIR Stent Literally Has a "Substantially Uniform Thickness."

The Court should grant BSC JMOL of noninfringement of claim 23 because there is no legally sufficient evidence to support the infringement verdict that the NIR stent literally satisfies the claim limitation that requires the "wall" defined by the "wall surface disposed between the first and second ends" of the "tubular member" to have a "substantially uniform thickness."[2]

Cordis's evidence of infringement was limited to proof about the uniform thickness of the wall of the individual struts of the NIR stent and the flat sheet of starting material from which the NIR stent is made, not the thickness of the "wall" defined by the "wall surface" of the "tubular member" of the NIR stent. Cordis did not submit *any* evidence about the uniformity of the thickness of the "wall" of the "tubular member" of the NIR stent and also did not challenge or respond to BSC's evidence the thickness of this "wall" is not "substantially uniform" because of the thickness variations created by the protruding U-loops, which exceed the 100% outer limit of the Court's claim construction.

A. The Infringement Issue Was Whether the Thickness of the "Wall" Defined By the "Wall Surface" of the "Tubular Member" of the NIR Stent, Not the Wall of the Individual Struts or Starting Material, Is "Substantially Uniform."

The infringement issue for the jury to decide was whether the "wall" defined by the

[2] Judgment as a matter of law is appropriate if "there is no legally sufficient evidentiary basis for a reasonable jury to find for [a] party on that issue." Fed. R. Civ. P. 50(a)(1); *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984). Judgment as a matter of law of noninfringement is appropriate if the evidence of infringement is not legally sufficient to support the infringement verdict. *TI Group Auto. Sys. (N. Am.), Inc. v. VDO N. Am., L.L.C.*, 375 F.3d 1126, 1133 (Fed. Cir. 2004).

"wall surface" of the "tubular member" of the NIR stent is "substantially uniform," *not* whether the thickness of the wall of the individual struts of the NIR stent or the flat sheet of starting material from which the NIR stent is made is "substantially uniform." This is clear from the claim language, the Federal Circuit's decision, this Court's claim construction at trial, and Cordis's prosecution arguments during the reexamination.

1. The Claim Language Requires the "Wall" Defined By the "Wall Surface" of the "Tubular Member" To Have a "Substantially Uniform Thickness."

The claim language requires the "wall" defined by the "wall surface" of the "tubular member," not the wall of the individual struts or the starting material, to have a "substantially uniform thickness." Claim 13 (from which claim 23 depends) covers an "expandable intraluminal vascular graft" comprising a "tubular member" with certain precise structural features, one of which is that the "*wall surface* disposed between the first and second ends" of the "tubular member" must have a "substantially uniform thickness":

> 13. An expandable intraluminal vascular graft, comprising:
> a thin-walled *tubular member* having first and second ends and *a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness* …

PX-3 ('762 patent), col. 11, ll. 63-67 (emphasis added).

2. The Federal Circuit's Decision Explains That the Thickness of the "Wall" of the "Tubular Member" Is the Radial Distance Between the Outer Surface of the "Tubular Member" and the Surface of a Cylinder Inside the "Tubular Member."

The Federal Circuit's decision in the Cordis-AVE appeal also requires the thickness of the "wall" defined by the "wall surface" of the "tubular member," not the thickness of the wall of the individual struts or the starting material, to be "substantially uniform." The Federal Circuit explained that "it is the *wall surface* that needs to have a uniform thickness" and that the thickness of the "wall" defined by the "wall surface" is the radial distance between the

outer surface of the tubular member and the surface of a cylinder that would fit inside the tubular member: "The thickness of the *wall* is equal to . . . the distance between the outer point that intersects the wall surface and the corresponding inner point that intersects a similar imaginary cylindrical surface on the inside of the tubular member." *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1362 (Fed. Cir. 2003) (emphasis added).

The Federal Circuit also held that the "substantially uniform thickness" limitation requires this "wall" thickness to be "largely or approximately uniform" and that "a *wall* that varies in thickness by as much as 100 percent cannot be said to be of 'substantially uniform thickness' either literally or by equivalents." *Id.* at 1360, 1362 (emphasis added).

3. The Court's Claim Construction at Trial Required the Thickness of the "Wall" of the "Tubular Member" To Be "Substantially Uniform."

This Court's claim construction at trial, which was based on the Federal Circuit's decision, also required the thickness of the "wall" defined by the "wall surface" of the "tubular member," not the thickness of the wall of the individual struts or the starting material, to be "substantially uniform." The Court's jury instructions stated:

> "*Wall surface*" – The *outer surface* of the *tubular member* must be disposed in a common cylindrical plane.
>
> "Substantially uniform thickness" – The *wall* of a *tubular member* must be of largely or approximately uniform thickness. A *wall* that varies in thickness by as much as 100 percent cannot be said to be of substantially uniform thickness.

D.I. 1365 at 19-20; Tr. 1351:6-13 (emphasis added).

4. Cordis's Prosecution Arguments During the Reexamination Explain that the Thickness of the "Wall" of a "Tubular Member" With Twisted Struts Is Defined By the Twisted Orientation of Those Struts, Not the Thickness of the Wall of the Struts or the Starting Material.

Finally, Cordis's prosecution arguments also require the thickness of the "wall" defined by the "wall surface" of the "tubular member," not the thickness of the wall of the

individual struts or the starting material, to be "substantially uniform." During the reexamination of the '762 patent that Cordis conducted in 1998 in parallel with this litigation, Cordis clearly and unequivocally disavowed an interpretation which equates the thickness of the wall of the struts or the starting material with the thickness of the "wall" of the "tubular member" in a device in which the struts have twisted out of the plane of the starting material, such as the prior art Ersek device or the accused NIR stent.

During the reexamination, the examiner initially rejected several claims, including claims 13 and 23, as anticipated or obvious in view of the Ersek patent and stated that "Ersek shows an expandable graft or prosthesis 16 which meets *all of the structural limitations* in the claims," including the limitation that the "wall surface" of the "tubular member" must have a "substantially uniform thickness." PX-13, Tab 32 at 3015 (emphasis added).

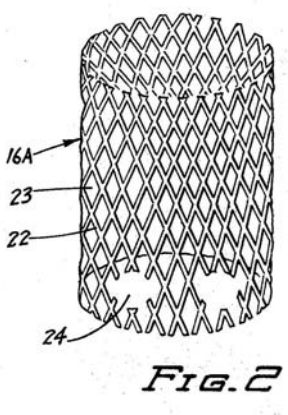


FIG. 2

FIG. 5

DX-15004 (Ersek patent), Figs. 2, 5.

The examiner concluded that the Ersek patent disclosed a tubular member with a uniform wall thickness by equating the thickness of the wall of the struts and the starting material of the Ersek device with the thickness of the "wall" of the tubular member and observing that, although the struts are twisted out of the plane of the starting material, they retain the same uniform thickness as the flat sheet from which the device is made:

> … [T]he thin walled *tubular member* (the Ersek fixation sleeve) and the elongate members (members 22 in the fixation sleeve) have a *uniform wall thickness since the members 22, although twisted, have the same thickness as the remainder of the sleeve*. In other words, *the sleeve is formed from a sheet of material having uniform thickness and the twisting of the members 22 does not change their thickness*.

PX-13, Tab 32 at 3009 (emphasis added).

In response, Cordis rejected the examiner's interpretation equating the thickness of the wall of the struts and the starting material with the thickness of the "wall" of the tubular member on the ground that the thickness of the "wall" of the Ersek "tubular member" was defined by the *twisted orientation* of the struts. Cordis argued that, even though the struts of the Ersek device have the same uniform thickness as the sheet from which the device is made, the "wall" of the Ersek "tubular member" varies in thickness because the struts have twisted out of plane:

> As shown … in Ersek Figure 5, in the first diameter configuration, the *wall* of sleeve 16 is of *varying thickness* because *the strands of the sleeve have twisted out of the plane of the starting material*. Moreover, the bonds or bridges at the junctions of the strands *protrude inwardly and outwardly of the plane of the starting material*, and as a result the Ersek sleeve 16 has a *non-uniform wall of varying thickness*.
>
> * * *
>
> Clearly, the Ersek sleeve cannot be fairly said to have a wall surface with a "substantially uniform thickness." … *The strands extending between the bridge portions are twisted to have inwardly and outwardly projecting edges. This irregular and variable configuration is rough and the antithesis of "substantially uniform thickness."* The use of the term "substantially uniform" does not exclude some variations in dimension between the inner and outer surfaces of the wall. Even so, it is clear that *Ersek's rough and irregular wall does not have substantially uniform thickness*.

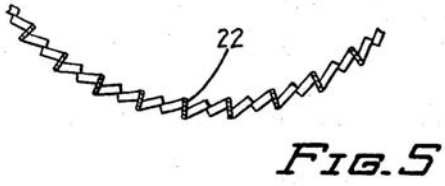


FIG. 5

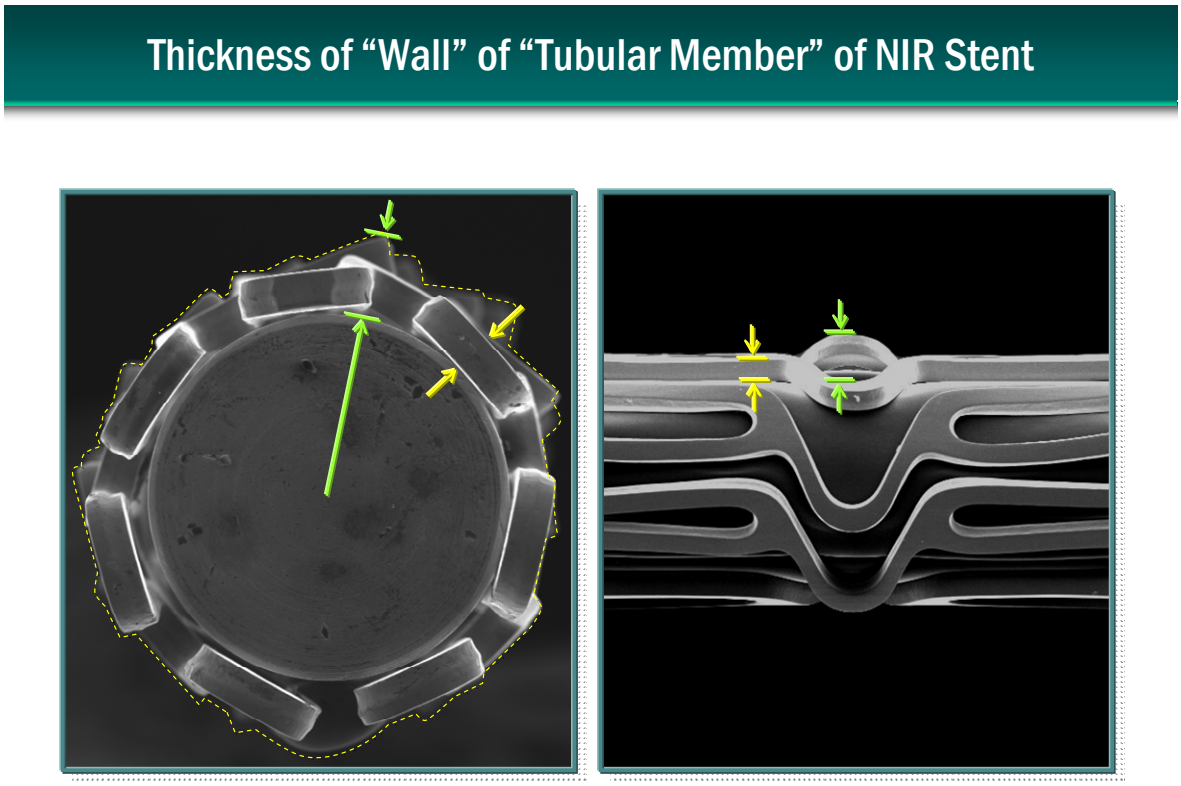
PX-13, Tab 36 at 3049, 3055 (emphasis added); DX-15004, Fig. 5.

By making these arguments, Cordis clearly and unequivocally disavowed any interpretation which equates the thickness of the wall of the struts or the starting material with the thickness of the "wall" of the "tubular member" in a device in which the struts have twisted out of the plane of the starting material, such as the Ersek device or the NIR stent. Cordis's arguments created a public record that in such a device, the thickness of the "wall" of the "tubular member" is not the thickness of the wall of the struts or the starting material but instead is the thickness of the cylindrical envelope defined by the twisted struts. In other words, Cordis told the Patent Office and the public that the twisted orientation of the struts, not the thickness of the wall of the individual struts or the starting material, determines the thickness of the "wall" of the "tubular member," and that a device with twisted struts that create substantial variations in the thickness of this "wall" is *not* within the scope of the claimed invention. *See Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304 (Fed. Cir. 1997) ("[B]y distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover.").

B. The Thickness of the "Wall" of the "Tubular Member" of the NIR Stent Is the Radial Distance Between the Outer Surface of the Stent and a Cylinder Inside the Stent, Not the Thickness of the Wall of the Individual Struts or the Starting Material.

The structure on the NIR stent which corresponds to the claimed "wall surface disposed between the first and second ends" of the "tubular member" is the outer surface of the NIR stent along the entire length between both ends of the stent. Since the U-loops on the NIR stent protrude beyond the surrounding outer surface of the stent, just like the twisted struts in the Ersek device, the thickness of the "wall" defined by this "wall surface" is not the thickness of the wall of the individual struts of the NIR stent or the starting material. Instead, as the claim language, the Federal Circuit's decision, the Court's claim construction, and Cordis's

prosecution arguments make clear, the thickness of this "wall" is the radial distance between the outer surface of the NIR stent and an inner cylinder that would fit inside the stent, as illustrated using the following scanning electron micrographs (SEMs) of the NIR stent:



Source: DXB 15067, 15061

DX-15061; DX-15067. Thus, the infringement issue for the jury to decide was whether *this radial distance* was literally "substantially uniform" along the entire length of the NIR stent, not whether the thickness of the wall of the individual struts or starting material of the NIR stent was "substantially uniform."

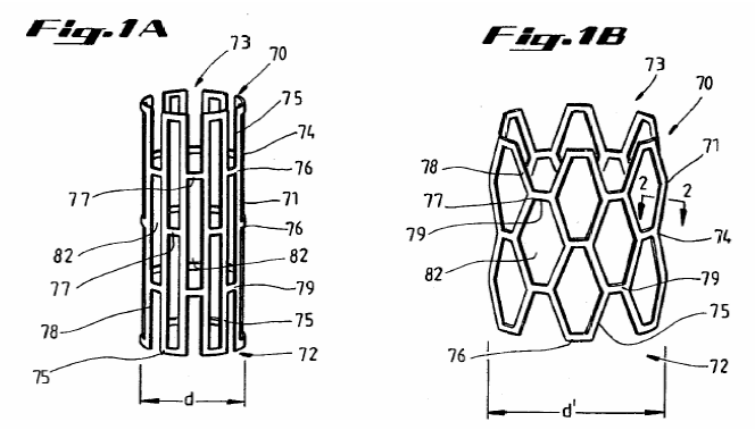
C. Cordis's Infringement Theory Was Based on the '762 Patent's Preferred Embodiment In Which the Thickness of the "Wall" of the Strut Is the Same As the Thickness of the "Wall" of the "Tubular Member."

Cordis's infringement theory at trial was that the NIR stent infringed because the uniformly thick wall of the individual struts and starting material of the NIR stent was the "wall" defined by the "wall surface" of the "tubular member" that had to have a "substantially

uniform thickness." Cordis's infringement theory was based on a description in the specification of the '762 patent of the preferred embodiment of the "tubular member" in which the thickness of the wall of the struts is the same as the thickness of the "wall" of the "tubular member" *because* the struts are not twisted out of plane but instead are part of a perfectly uniformly thick hollow tube into which slots are cut. That description does not describe a device such as the Ersek device or the NIR stent in which the struts protrude out of the cylindrical plane.

Cordis's infringement theory that the wall of the struts and the starting material is the same as the "wall" defined by the "wall surface" of the "tubular member" was based on the following description in the specification of the preferred embodiment of Figures 1A and 1B, for which the thickness of the wall of the individual struts (the individual "members" identified by reference numerals 75, 77, 78 and 79) is *the same* as the thickness of the "wall surface" of the "tubular member":

> The expansion of tubular member 71 into the configuration shown in FIG. 1B is further uniform along the length of tubular member 71, not only because of the uniform spacing between slots 82, as previously described, but also because *the thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79, is the same uniform thickness.*



PX-3, col. 7, ll. 26-33 (emphasis added); Figs. 1A and 1B. Based on this description of the preferred embodiment, Dr. Buller testified that the thickness of the "wall" of the NIR stent for

purposes of the "substantially uniform thickness" limitation in claim 23 was the thickness of the struts:

> Q. Okay. And does the patent identify what it is one measures to identify the thickness of the wall surface?
>
> A. Oh, very explicitly. The patent teaches and actually shows a diagram where *you take a cross-section of the metal the stent is made from and it shows that as being the wall thickness.*
>
> Q. We've got the text of the patent against the figure. Let me just read the language and you can comment upon it.
>
> The thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79, is the same uniform thickness.
>
> What is Palmaz saying there?
>
> A. . . . So he's teaching in the text and showing you exactly what he means. *He means the thickness the metal of the stent, if it's made from metal.* If it's made from a different material, he means the thickness of that material and *he means that that should be the same uniform thickness.*

Tr. 426:18-27:23 (emphasis added).

> Q. Can you identify on the picture above where the walls of the NIR stent are?
>
> A. Yes. *The walls are the metal of the stent.* It's not a very big picture and this is part of one stent, but *you can see the sort of thickness of the – of the metal that's making up the stent.* And you can see on this picture that wherever you can see it, sort of side-on or approaching side-on, *it is the same metal thickness.*

Tr. 429:5-12 (emphasis added). Cordis's counsel repeated this argument by telling the jury that "[t]he thickness of the wall of the NIR stent is the thickness of its metal. That's what Dr. Palmaz tells us." Tr. 1211:19-21; *see also* Tr. 1209:21-11:21.

Cordis's infringement theory cannot support the verdict because the proposition that the thickness of the wall of the individual struts of the NIR stent defines or is the same thing as the thickness of the "wall" defined by the "wall surface" of the "tubular member" is inconsistent with the claim language, the Federal Circuit's decision, the Court's claim

construction, and Cordis's prosecution arguments. The thickness of the "wall" of the "tubular member" of the preferred embodiment of Figure 1 happens to be the same thickness as the thickness of the struts because that embodiment is manufactured by cutting slots into a hollow tube that has a perfectly uniform wall thickness:

> Preferably, tubular member 71 is initially a *thin-walled stainless steel tube having a uniform wall thickness*, and a plurality of slots 82 are formed in the wall surface 74 of tubular member 71.

PX-3, col. 6, ll. 41-44. As Cordis itself argued during prosecution, the thickness of the wall of the individual struts or the starting material is *not* the same as the thickness of the "wall" of a "tubular member" which is *not* cut from a tube but instead is made in a way that results in struts twisted out of the cylindrical plane, such as the Ersek device or the NIR stent. For those devices, the claim language, the Federal Circuit's decision, this Court's claim construction, and Cordis's prosecution arguments each make clear that the thickness of the "wall" of the "tubular member" is the thickness of the cylindrical envelope defined by the twisted orientation of the struts, not the thickness of the wall of the strut. *See Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers." (citation omitted)).

D. Cordis's Infringement Evidence Cannot Support the Verdict Because It Was Limited To Proof That the Wall of the Struts of the NIR Stent and the Starting Material, Not the "Wall" Defined By the "Wall Surface" of the "Tubular Member," Are Uniformly Thick.

Cordis's evidence at trial cannot support the infringement verdict because it was limited to proof that the wall of the individual struts of the NIR stent and the starting material, not the "wall" defined by the "wall surface" of the "tubular member" of the NIR stent, are uniformly thick. For example, Dr. Buller testified as follows:

> Q. Doctor, does the fact that the U sticks out slightly have any bearing on the thickness of the walls of the NIR stent?
>
> A. It has absolutely no bearing on the thickness. I mean, yes, they do protrude a very small amount, as you can see, but they are of exactly the same thickness. This does not alter the thickness. The thickness of the metal here is exactly the same at the tip of the U.

Tr. 459:10-17; *see also* Tr. 112:22-14:3; 116:7-17:7; 428:23-30:9; 432:15-33:23; 436:18-43:10; 452:15-53:9; 457:25-58:10; 464:22-65:6; 850:11-51:18; 859:4-62:24; 863:3-66:15; 975:8-77:7; 989:19-90:18; 993:3-94:10; 1211:22-17:18; 1221:6-25:11; 1225:23-26:14; 1298:5-1302:7; PX-339; PX-7207; PX-7236; PX-7800; PX-7801; PX-7803. Cordis offered its irrelevant evidence about the thickness of the wall of the struts of the NIR stent or the starting material in four categories:

First, Cordis offered evidence about measurements in internal BSC engineering drawings and documents, and the *Handbook of Coronary Stents*, which showed that the thickness of the struts of the NIR stent and/or the flat sheet from which the NIR stent is made is uniform. *See* Tr. 112:22-14:3; 116:7-17:7; 437:24-40:5; 859:4-62:24; 989:19-90:19; 1211:22-14:21; 1216:11-17:18; PX-339; PX-7207; PX-7801; PX-7800; PX-7803.

Second, Cordis offered evidence about measurements of the NIR stent taken by BSC engineers for Dr. Snyder which showed the thickness of the wall of the struts to be uniform. *See* Tr. 112:22-14:3; 440:6-43:10; 967:9-68:6; 1006:4-08:19; 1225:23-26:14; PX-7236.

Third, Cordis tried (unsuccessfully) to impeach Dr. Richter and Dr. Snyder with deposition testimony by Mr. Brown, a BSC engineer, that the strut thickness of the NIR stent is uniform and that the protrusion of the U-loops on the NIR stent is "minor." *See* Tr. 863:3-66:15; 975:8-77:7; 1214:22-16:10; 1221:6-22:5; 1299:2-4; 1299:14-19; PX-339.

Finally, Cordis tried (unsuccessfully) to impeach Dr. Snyder with deposition testimony by Dr. Low about the thickness of the struts in an unidentified hypothetical stent, which had

nothing to do with the claim language, the claim construction or the NIR stent. *See* Tr. 993:3-94:10; 1222:20-23:4; 1224:18-25; 1300:21-01:1.

Apart from all of this legally irrelevant evidence about the thickness of the wall of the struts or the starting material, Cordis did not offer *any* evidence at trial about the thickness of the "wall" defined by the "wall surface" of the "tubular member" of the NIR stent to carry its burden of proof on infringement.

Moreover, Cordis did not challenge or respond to BSC's extensive evidence and testimony by Dr. Richter and Dr. Snyder that the thickness of the "wall" defined by the "wall surface" of the "tubular member" of the NIR stent is not "substantially uniform" because of the thickness variations created by the protruding U-loops, which exceed the 100% outer limit of the Court's claim construction. *See* Tr. 772:5-18; 775:2-77:1; 778:11-81:10; 799:20-801:8; 853:9-54:22; 870:10-21; 936:9-40:4; 959:15-60:9; 968:7-69:15; 1078:22-80:5; DX-15050; DX-15053; DX-15054; DX-15061; DX-15067; DX-15069; DX-15078; DX-15083.

Since there is no legally sufficient evidence to support the verdict that the thickness of the "wall" of the "tubular member" of the NIR stent literally is "substantially uniform," the Court should grant BSC JMOL of noninfringement.

II. If the Court Does Not Grant BSC JMOL of Noninfringement, It Should Grant BSC a New Infringement Trial.

A. A New Trial Is Warranted Because It Was Prejudicial Error To Instruct the Jury During Deliberations That the "Wall Surface" Limitation Was Not In Dispute And To Fail To Keep a Record of That Instruction.

The Court should grant BSC a new infringement trial because it was prejudicial error to erroneously instruct the jury at a critical point during the jury's deliberations to the effect that the "wall surface" limitation was not in dispute, and to do so without keeping a written record of the precise language of that instruction, when the correct identification of the "wall surface" was intensely disputed and critical to whether the "substantially uniform thickness"

limitation was met.

1. The Erroneous Instruction That the "Wall Surface" Limitation Was Not In Dispute Was Extremely Prejudicial Because It Diverted the Jury From the Correct Infringement Issue and Bolstered Cordis's Infringement Theory.

As explained above, the infringement issue at trial was whether the thickness of the "wall" defined by the "wall surface" of the "tubular member" of the NIR stent is "substantially uniform." This issue turned on *identifying which structure* of the NIR stent corresponded, either literally or by equivalents, to the "wall" defined by the "wall surface" of the "tubular member" as defined by the Court. Cordis argued that the relevant "wall" was the wall of the individual struts of the NIR stent or starting material, and offered evidence, which BSC did not dispute, that the thickness of those struts and starting material is uniform. BSC argued that the relevant "wall" was not just the wall of the struts but rather the wall of the cylindrical envelope defined by the outer surface of the "tubular member" of the NIR stent, and offered evidence, which Cordis did not dispute, that the thickness of this wall varies by more than 100% because of the protruding U-loops.

Since the infringement issue turned on whether the "wall surface" of the NIR stent was only the wall of the individual struts, as Cordis argued, or the wall of the cylindrical envelope of the "tubular member," as BSC argued, the application of the "wall surface" limitation—which requires a "wall surface disposed between the first and second ends" of the "tubular member"—and of the Court's construction of that limitation—which requires that "[t]he outer surface of the tubular member must be disposed in a common cylindrical plane"—was *intensely disputed and critical* to whether the "substantially uniform thickness" limitation was met. Indeed, this was the only real dispute on infringement.

For purposes of this second trial, BSC and Cordis stipulated that the NIR stent satisfied the "wall surface" limitation, *either literally or by equivalents*. D.I. 1310, Tab 1, ¶ 8, 9. That

stipulation was based on the jury verdict at the first trial in 2000 that the NIR stent did *not literally infringe* claim 23 but did infringe under the doctrine of equivalents. D.I. 182 (in C.A. 98-197). Despite Cordis's repeated arguments at trial (Tr. 671:18-85:8; 820:22-28:24; 1204:24-25) and during deliberations (Tr. 1381:3-82:5; 1383:22-84:16) to the contrary, there has *not* been any adjudication or admission by BSC that the NIR stent *literally* satisfies the "wall surface" limitation requiring the "outer surface of the tubular member [to] be disposed in a common cylindrical plane." Indeed, BSC asserted at the first trial in 2000 and continues to assert that the NIR stent does not literally satisfy this definition because the U-loops and welds protrude beyond any such common cylindrical plane.[3]

During its deliberations, the jury clearly understood that the infringement issue turned on identifying the structure of the NIR stent that corresponded to the claimed "wall surface." After deliberating for almost five hours over two days, the jury sent a note to the Court asking if the Court could "clarify further the words 'disposed' and 'common cylindrical plane' and the definition of 'wall surface.'" Tr. 1378:8-18. This question reveals that the jury was struggling with how to apply the Court's definition of "wall surface," which requires the outer surface to be "disposed in a common cylindrical plane," to the irregular outer surface of the NIR stent.

During the teleconference with counsel, Cordis argued that the jury's question showed that the jury was improperly analyzing whether the NIR stent satisfied the "wall surface" limitation and demanded that the Court go beyond responding to the jury's question and instruct them that the "wall surface" limitation was not in dispute. Tr. 1379:1-18; 1381:3-82:5.

[3] BSC also contends that prosecution history estoppel based on Cordis's distinction of the prior art Ersek patent during the '762 reexamination bars Cordis from asserting infringement of the "wall surface" limitation under the doctrine of equivalents.

In response, BSC objected to that new instruction as incorrect, unnecessary and prejudicial because the jury's question actually demonstrated that the jury was correctly attempting to identify the structure on the NIR stent that corresponded to the claimed "wall surface" in order to correctly analyze the infringement issue of whether the thickness of *that structure* was "substantially uniform." Tr. 1379:19-81:2; 1382:6-83:4; 1383:8-21. Over BSC's objection, the Court indicated that it would instruct the jury that the "wall surface" limitation was not in dispute and that the only dispute related to "substantially uniform thickness":

> MR. DISKANT: … I want to be sure what your Honor was going to say. I hope you would. *That the wall surface limitation is not disputed in this case*, and *the only dispute relates to the substantially uniform thickness limitation.*
>
> THE COURT: *That is what I plan to say*.

Tr. 1386:7-14 (emphasis added). Shortly after the Court instructed the jury, the jury returned an infringement verdict for Cordis. Tr. 1387:2-88:24.

As explained below, there is no record of the precise language of the Court's communication with the jury. Assuming that the Court instructed the jury to the effect that the "wall surface" limitation was not in dispute, that instruction at this critical point during deliberations was erroneous, unnecessary and very prejudicial.

The instruction was erroneous and unnecessary because the jury's question requesting clarification about the meaning of the Court's definition of "wall surface" did *not* demonstrate, as Cordis argued, that the jury was improperly analyzing whether the NIR stent satisfied the "wall surface" limitation. No evidence or argument had been offered on that issue at trial and the jury had already been clearly and unequivocally instructed that the *only* infringement issue was whether the NIR stent satisfied the "substantially uniform thickness" limitation. Tr. 847:13-18; 1347:14-20; 1353:21-55:4; D.I. 1365 at 15, 22-23.

To the contrary, the jury's question demonstrated that the jury was correctly attempting

to *identify the structure* on the "tubular member" of the NIR stent that corresponds to the claimed "wall surface" in order to correctly analyze *whether the thickness of that structure* was "substantially uniform." The issue of what structure on the NIR stent corresponded to the claimed "wall surface" that is required to have a "substantially uniform thickness" *was critical and very much in dispute*. The jury understood that this was the critical issue and was correctly weighing Cordis's theory that the strut thickness was the correct measure of "wall" thickness against BSC's theory that the thickness of the cylindrical envelope created by the outer surface that defines the "wall surface" was the correct measure of "wall" thickness.

By instructing the jury during deliberations, the Court changed the jury instructions by adding a *new* instruction to the effect that the "wall surface" limitation was not in dispute. This new instruction on this critical and intensely disputed issue at a critical point during the jury's deliberations severely prejudiced BSC. The instruction effectively instructed the jury just to focus on "substantially uniform thickness" and not to concern itself with the "wall surface" limitation and the Court's claim construction of that term, both of which were critical to the jury's task of identifying what structure on the NIR stent corresponded to the "wall surface" that was required to have a "substantially uniform thickness." Moroever, the instruction improperly diverted the jury from the correct infringement issue with which they were struggling by implying that their effort to try to understand what structure corresponded to the "wall surface" limitation was unnecessary and irrelevant because it was not in dispute, which bolstered Cordis's theory that the defined structure did not matter and that the NIR stent infringes because of its uniform strut thickness.

Further, even though BSC and Cordis had stipulated that the NIR stent may only have the *equivalent* of a "wall surface," the new instruction during deliberations that the "wall surface" limitation was not in dispute effectively instructed the jury, which had not received

any instruction on the doctrine of equivalents, that the outer surface of the NIR stent *literally* is "disposed in a common cylindrical plane." This effectively instructed the jury to ignore the deviations from a "common cylindrical plane" along the outer surface created by the protruding U-loops as not forming part of the "wall surface," which bolstered Cordis's infringement theory by making the protruding U-loops appear trivial and irrelevant to whether the "wall surface" has a "substantially uniform thickness." It was especially prejudicial to effectively instruct the jury that the outer surface of the NIR stent literally is "disposed in a common cylindrical plane" when there has not been any finding or admission to that effect and BSC vigorously disputes this.

A prejudicially erroneous jury instruction is grounds for a new trial. *Ecolab, Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1373 (Fed. Cir. 2002); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1281 (Fed. Cir. 2000); *Weinar v. Rollform, Inc.*, 744 F.2d 797, 808 (Fed. Cir. 1984). The Court should grant BSC a new infringement trial because the Court's new, erroneous and unnecessary instruction that the "wall surface" limitation was not in dispute at a critical point during the jury's deliberations when the jury was considering precisely that disputed issue was extremely prejudicial. It manifestly cannot be said that the instruction was harmless in that it "could not have changed the result" or that "the same verdict would necessarily" have been reached without the instruction or that it is "highly probable" that the instruction did not affect the outcome. *Ecolab*, 285 F.3d at 1374; *Weinar*, 744 F.2d at 808; *McQueeney v. Wilmington Trust Co.*, 779 F.2d 916, 928 (3d Cir. 1985).

2. The Erroneous Failure to Keep a Record of the Communication With the Jury Compounds the Prejudice of the Erroneous Instruction By Impairing BSC's Ability to Seek Review of the Verdict.

It was a separate prejudicial error to fail to keep a written record of the instruction to the jury during deliberations. The absence of any record of the precise language of the Court's

communication with the jury compounds the prejudice of the erroneous instruction by impairing BSC's ability to seek post-trial and appellate review of the verdict.

Although the Court had indicated during the teleconference that it would send a written response to the jury by stating that "I will get this note back to the jury" (Tr. 1385:17), no such note was in the record. BSC also discovered after the verdict that there was no transcript or other record of the Court's response to the jury. The Court's communication with the jury did not appear on the trial transcript for the day in question and there was no record of a written communication on the docket. Counsel for BSC inquired of the Court's chambers about any other record and was told that there was none. As such, there was no record of precisely what the Court communicated to the jury. The only record of the Court's communication to the jury on this critical and disputed issue was the general nature of the Court's proposed instruction as recorded during the teleconference with counsel. Tr. 1378-86.

The failure to keep a record of the *ex parte* communication with the jury was error and warrants a new trial because this error was prejudicial. *See Skill v. Martinez*, 677 F.2d 368, 371 (3d Cir. 1982) (*citing Arrington v. Robertson,* 114 F.2d 821, 822-23 (3d Cir. 1940)); *see also Fillippon v. Albion Vein Slate Co.*, 250 U.S. 76, 81 (1919).[4, 5] The absence of any written record of the Court's communication impairs BSC's ability to seek post-trial and appellate

[4] A Court's oral *ex parte* communication with a jury may be reversible error. *See*, *e.g.*, *U.S. v. Cowan*, 819 F.2d 89, 94 (5th Cir. 1987) ("Absent … compelling circumstances, communication between the court and a deliberating jury should be either in writing or in open court."); *see also U.S. v. U.S. Gypsum Co.*, 438 U.S. 422, 460 (1978) ("Any *ex parte* meeting or communication between the judge and the foreman of a deliberating jury is pregnant with possibilities for error … [E]ven an experienced trial judge cannot be certain to avoid all the pitfalls inherent in such an enterprise.").

[5] A Court's failure to record its communication with the jury in open court would violate the Court Reporter's Act and be reversible error if prejudicial. *See Veillon v. Exploration Servs., Inc.*, 876 F.2d 1197, 1200 (5th Cir. 1989); *see also* 28 U.S.C. § 753(b) ("Each session of the court … shall be recorded verbatim … includ[ing] … (2) all proceedings … had in open court...").

review of the verdict. Without a record, BSC, this Court and the Federal Circuit cannot evaluate the prejudice of the precise language used by the Court on this critical and disputed issue at this critical point during the jury's deliberations. *See U.S. v. Ronder*, 639 F.2d 931, 935 (2d Cir. 1981) ("[A]t this critical stage of the trial the wording may be as significant as the substance of the response."). The absence of a written record means that any evaluation of prejudice necessarily is limited to evaluating the prejudice of the substance of the Court's proposed instruction as recorded during the teleconference. As explained above, the substance and timing of that proposed instruction was erroneous and severely prejudicial. Even if a reviewing court were to find no error in the general substance of the proposed instruction, it may find error in the specific words used by the Court to convey the substance. Depending on the precise language used, the Court's actual communication with the jury may have exacerbated the prejudice, but this additional prejudice cannot be evaluated because of the absence of a written record. This is manifestly unfair and unjust. It also violates BSC's Seventh Amendment right to a jury trial, which contemplates that the jury will receive appropriate instructions. *See Gasoline Prods. Co. v. Champlin Refining Co.*, 283 U.S. 494, 498 (1931). BSC should be granted a new infringement trial.

B. A New Trial Is Warranted Because It Was Reversible Error For Cordis to Introduce and Rely On Undesignated Deposition Testimony As Substantive Evidence In Order to Mislead the Jury Into Believing That BSC Had Admitted Infringement.

The Court should also grant BSC a new infringement trial because it was reversible error for Cordis to refer during closing arguments to undesignated deposition testimony by Mr. Brown and Dr. Low as substantive evidence in order to mislead the jury into believing that BSC admitted that the NIR stent infringes the "substantially uniform thickness" limitation. Tr. 1209:4-14; 1214:22-16:10; 1221:6-23:4; 1224:18-25; 1299:2-1301:1; 1302:1-7.

A new trial is warranted where a closing argument refers to prejudicial extraneous

evidence that goes beyond the admitted evidence and reasonable inferences drawn from that evidence. *Fineman v. Armstrong World Industries, Inc.*, 980 F.2d 171, 210 (3d Cir. 1992) ("[A]rgument injecting prejudicial extraneous evidence constitutes reversible error."); *Ayoub v. H.N. Spencer*, 550 F.2d 164, 170-71 (3d Cir. 1977) (a new trial is appropriate if a closing argument refers to extraneous matter that is not admitted into evidence and this had "a reasonable probability of influencing the verdict").

The deposition testimony of Mr. Brown and Dr. Low to which Cordis's counsel referred during his closing argument was not admitted as substantive evidence; the testimony was used solely for impeachment purposes during the cross-examinations of Dr. Richter and Dr. Snyder. Tr. 863:6-66:15; 975:17-77:7; 993:3-94:10.[6] The only evidence to which Cordis's counsel should have referred during his closing argument was the answers of BSC's witnesses, not the deposition testimony of Mr. Brown and Dr. Low or counsel's questions quoting that testimony. *U.S. v. Barber*, 442 F.2d 517, 523 (3d Cir. 1971) ("[S]worn testimony

[6] Although Cordis argued at trial that Mr. Brown's deposition testimony was admissible as an admission, Cordis never made the necessary showing that the testimony qualifies as an admission under Fed. R. Civ. P. 32, which controls the admissibility of depositions at trial. *See Allgeier v. United States*, 909 F.2d 869, 876 (6th Cir. 1990) ("The party seeking to admit a deposition at trial must prove that the requirements of Rule 32(a) have been met."); *see also Schneider v. TWR, Inc.*, 938 F.2d 986, 1001 (9th Cir. 1991) ("[Fed. R. Evid.] 801 therefore does not control the admissibility of depositions; rather, Rule 32 of the Federal Rules of Civil Procedure controls."). This Court never ruled that Mr. Brown's testimony was admissible as an admission. Tr. 863:6-64:16; 975:18-76:1. Mr. Brown's testimony was not admissible under Rule 32(a)(2) because he was not an officer or director and he did not qualify as a "managing agent." Mr. Brown was not, as Cordis argued, the "engineer who [was] deciding whether to buy the [NIR] product." Tr. 1221:6-14. He merely conducted preliminary testing on the NIR stent and did not make any corporate decision about whether to purchase the NIR technology from Medinol. *See* 7/29/99 Brown Dep. Tr. at 30:9-21 (attached as Ex. A); *see also, e.g., Young & Assocs. Pub. Relations v. Delta Air Lines, Inc.*, 216 F.R.D. 521, 524 (C.D. Utah 2003) (finding that individuals who "lacked discretion to make decisions for the corporation without approval and authorization from higher authority" were not "managing agents" under Rule 32(a)(2)); *Reed Paper Co. v. Proctor & Gamble Dist. Co.*, 144 F.R.D. 2, 4-6 (D. Me. 1992) (finding that an individual who "simply provide[d]

received in open court" is admitted evidence); *United States v. Quintero*, 38 F.3d 1317, 1340 (3d Cir. 1994) ("[Q]uestions of lawyers do not themselves constitute evidence.").

It was very prejudicial for Cordis's counsel, over BSC's objection (Tr. 1227:24-28:10), to treat Mr. Brown's and Dr. Low's deposition testimony as substantive evidence during his closing argument, by repeatedly referring to this testimony and telling the jury to consider this "evidence" when it was not admitted evidence, and without ever mentioning the answers of the witnesses Cordis's counsel had sought to impeach. Tr. 1209:4-14; 1214:22-16:10; 1221:6-23:4; 1224:18-25; 1299:2-1301:1; 1302:1-7. This was prejudicial because Cordis mischaracterized the testimony of Mr. Brown and Dr. Low to mislead the jury into believing that BSC admitted that the NIR stent infringes the "substantially uniform thickness" limitation.

Cordis's counsel mischaracterized Mr. Brown's deposition testimony to undercut Dr. Richter's and Dr. Snyder's testimony by misleading the jury into believing that BSC had admitted that the thickness of the "wall" of the NIR stent is the uniform strut thickness and that the flaring of the U-loops in the unexpanded NIR stent is trivial. Tr. 1209:4-14; 1214:22-16:10; 1221:6-22:5; 1299:2-19; PX-339. Mr. Brown's testimony about uniform thickness related to strut thickness and had nothing to do with the claim language or the Court's claim construction years later. Tr. 863:3-66:15; 7/27/99 Brown Dep. Tr. 184:5-89:17 (attached as Ex. B). Further, it is at best unclear whether Mr. Brown's testimony about the flaring of the U-loops on the NIR related to the unexpanded NIR stent, in which the U-loops protrude, or the expanded NIR stent, in which the U-loops are designed not to protrude. Tr. 975:8-77:7; 1/30/01 Brown Dep. Tr. 101:3-15 (attached as Ex. C).[7]

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assessments and recommendations" and who had no "general power to exercise his discretion and judgment in dealing with corporate matters" was not a "managing agent").

[7] Although Mr. Brown's testimony is ambiguous, the surrounding testimony about the protrusion of U-loops into the lumen in *expanded* stents suggests that his testimony related to

Cordis's counsel also mischaracterized Dr. Low's deposition testimony to undercut Dr. Richter's and Dr. Snyder's testimony by misleading the jury into believing that Dr. Low had admitted that the thickness of the "wall" of the NIR stent is the strut thickness. Tr. 1222:20-23:4; 1224:18-25; 1300:21-01:1. In fact, Dr. Low's testified immediately following the testimony used by Cordis at trial that the struts and the "wall" of the stent are different:

> Q. Would you consider the metal from which a stent is constructed to be the wall of a stent?
>
> A. No.
>
> Q. Why not?
>
> A. *Well the metal is the metal and, you know, "wall" is, it is a completely different concept.*

11/10/04 Low Dep. Tr. 63:12-20 (emphasis added) (attached as Ex. D).

By using Mr. Brown's and Dr. Low's deposition testimony as substantive evidence, Cordis also violated the stipulated designation procedures set forth in the pretrial order (D.I. 1310, Tab 1, ¶ VII.3) and the doctrine of completeness under Fed. R. Civ. P. 32(a)(4), which required Cordis to provide BSC with sufficient notice of its intention to introduce deposition testimony as substantive evidence, so that BSC had the opportunity to counter-designate "any other part [of the deposition] which ought in fairness to be considered with the part introduced." Fed. R. Civ. P. 32(a)(4). By failing to follow this procedure, Cordis unfairly deprived BSC of the opportunity to counter-designate additional testimony to eliminate or mitigate the impact of Cordis's mischaracterizations of the testimony.

By repeatedly telling the jury to consider the substance of Mr. Brown's and Dr. Low's deposition testimony and by misleading the jury as to the import of that testimony, it is very

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the expanded NIR stent, not the unexpanded NIR stent. *See* Ex. C at Tr. 81:12-25; 86:18-23; 101:16-22; 103:16-105:5; 121:25-122:8.

likely that Cordis confused the jury and caused them to improperly give weight to this testimony as substantive evidence in arriving at their infringement verdict. This warrants a new infringement trial. *See Ayoub*, 550 F.2d at 170-71.

C. A New Trial Is Warranted Because the Infringement Verdict Is Against the Weight of the Evidence.

Finally, if the Court does not grant JMOL of noninfringement, the Court should grant BSC a new infringement trial because the verdict is against the weight of the evidence, for the reasons set forth in BSC's argument for JMOL of noninfringement. *See* Section I *supra*; *see also Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1352 (3d Cir. 1991).

III. The Court Should Grant BSC Judgment As a Matter of Law of Invalidity Because The Verdict That the Device of Claim 23 Was Not Obvious In View of the Ersek Device Cannot Be Supported Because BSC's Evidence That It Was Obvious Was Clear and Convincing and Not Challenged By Cordis.

BSC should be granted JMOL of obviousness of claim 23 because BSC's evidence of obviousness was clear and convincing and not challenged by Cordis.[8]

Claim 23 is a *device* claim to an expandable graft. Therefore, the patentability of the claim depends on the patentability of the claimed *structure*. BSC's evidence that that the claimed *device* is almost identical to the prior art Ersek *device*, that the minor differences between those two *devices* were so trivial that the claimed *device* would have been obvious, and that one of ordinary skill in the art would have been motivated to modify the Ersek *device* to arrive at the claimed *device*, was both sufficient to meet BSC's clear and convincing burden and also not challenged by Cordis. None of Cordis's evidence related to whether the claimed *device* would have been obvious in view of the Ersek *device*. Instead, it was limited to

[8] Judgment as a matter of law of obviousness is appropriate if the evidence of nonobviousness is not legally sufficient to support the nonobviousness verdict. *Sjolund v. Musland*, 847 F.2d 1573, 1576 (Fed. Cir. 1988).

irrelevant proof that the *combination* of a stent on a balloon and the noninvasive *method* of intraluminally delivering and expanding a stent on a balloon—neither of which is claimed in claim 23—would not have been obvious in view of the invasive surgical *method* disclosed in the Ersek patent.

A. Since Claim 23 Is a Device Claim, Its Patentability Depends on Whether the Structure of the Claimed Device Would Have Been Obvious In View of the Ersek Device.

Claim 23 is a claim to a *device*. The claim covers an "expandable intraluminal vascular graft" comprising a "tubular member" with certain structural features and properties: The "tubular member" must be "thin walled" and have a "wall surface" with a "substantially uniform thickness," a "smooth surface" and a "plurality of slots formed therein" that are disposed "substantially parallel to the longitudinal axis." The tubular member must have a "first diameter" which is small enough to "permit intraluminal delivery of the tubular member into a body passageway having a lumen." The tubular member also must be capable of being controllably expanded from the first diameter to a "second, expanded and deformed diameter" by applying "a radially, outwardly extending force" from the inside of the tubular member. *See* PX-3, col. 11, l. 62 to col. 12, l. 13; col. 12, ll. 56-59.

Unlike other unasserted claims of the '762 patent, claim 23 does *not* cover a combination of a stent on a balloon or a method of intraluminally delivering, expanding and implanting a stent on a balloon. In particular, claim 23 does not state that the tubular member actually must be intraluminally delivered into a body passageway on a balloon catheter or any other delivery device; it simply states that the tubular member must have a first diameter which is small enough to permit intraluminal delivery. Claim 23 also does not state that the tubular member actually must be expanded by a balloon or any other device inside a body passageway; it simply states that the tubular member must be capable of being controllably

expanded to a second diameter by applying a force from the inside of the tubular member.

The preamble to claim 23, which recites "[a]n expandable intraluminal vascular graft, comprising," is not a claim limitation which requires the claimed graft to be used in a particular method involving intraluminal delivery and expansion on a balloon because "[the] patentee [has] define[d] a structurally complete invention in the claim body and use[d] the preamble only to state a purpose or intended use for the invention." *Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (*quoting Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)).

Since claim 23 is a device claim that is not limited to a particular use by the preamble, the patentability of the claim "depends on the claimed structure, not on the use or purpose of that structure." *Id.* at 809 (*citing In re Gardiner*, 171 F.2d 313, 315-16 (CCPA 1948)). Accordingly, the obviousness issue at trial was whether the *device* claimed in claim 23 would have been obvious in view of the Ersek *device*, not whether the *combination* of a stent on a balloon or the noninvasive *method* of intraluminally delivering and expanding a stent on a balloon would have been obvious in view of the invasive surgical *method* of Ersek. Since the patentability of claim 23 depends solely on the claimed structure, the differences between those two methods are irrelevant.

B. The Verdict Cannot Be Supported Because BSC's Evidence That the Claimed Device Would Have Been Obvious In View of the Ersek Device Was Clear and Convincing and Not Challenged By Cordis.

BSC introduced clear and convincing evidence that that the device of claim 23 is almost identical to the prior art Ersek device, that the minor differences between those two devices were so trivial that the claimed device would have been obvious, and that one of ordinary skill in the art in 1985 would have been motivated to modify the Ersek device to arrive at the claimed device. *See, e.g.*, Tr. 875:1-18; 881:20-82:1; 920:18-21:7; 929:2-49:15-

57:13; DX-15004.

Cordis did not challenge or respond to BSC's evidence or address whether the device claimed in claim 23 would have been obvious in view of the Ersek device. Instead, Cordis's evidence was limited to irrelevant proof that the combination of a stent on a balloon and the noninvasive method of intraluminally delivering and expanding a stent on a balloon—neither of which is claimed in claim 23—would not have been obvious in view of the invasive surgical method of Ersek. *See* Tr. 109:8-18; 111:17-19; 404:22-05:13; 412:1-13:8; 419:1-5; 466:15-67:4; 468:16-69:10; 492:21-500:12; 501:20-04:22; 505:21-06:5; 507:15-09:14; 525:24-26:8; 531:17-32:3; 659:8-60:11; 704:2-11; 1013:3-16:6; 1018:1-10; 1030:8-31:22; 1175:23-76:3; 1319:1-23; 1321:1-10.

Dr. Buller repeatedly testified about the differences between noninvasive intraluminal delivery and the invasive surgical method of the Ersek patent:

> Q. What's Ersek?
>
> A. … This is a surgical device to be used in a major surgical operation with a patient opened up. This had nothing to do with intraluminal delivery, the avoidance of surgery, the avoidance of excising, removing or any of the other features.

Tr. 492:21-93:12.

> Q. Is such a device appropriate for intraluminal delivery as Dotter and Gruntzig and Palmaz taught?
>
> A. It has nothing to do with intraluminal delivery. This is a surgical operative tool to try and replace a surgeon's sutures.

Tr. 500:5-9; *see also, e.g.*, Tr. 468:20-69:10; 492:21-500:12. When Dr. Buller purported to compare the elements of claim 23 to the Ersek patent, he compared intraluminal delivery to the surgical *method* of Ersek instead of comparing the device of claim 23 to the Ersek *device*:

> Q. Dr. Buller, have you prepared a series of slides showing the differences between the Ersek device and Dr. Palmaz's Claim 23?
> …

> First, an expandable intraluminal vascular graft. Is the Ersek device such a device?
>
> A. No. … It is not intraluminal in the sense that intraluminal non-surgical delivery. It is a device to be used in surgery, to fix something else in place. …

Tr. 501:20-02:11 (emphasis added).

> Q. … Whereas a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen.
>
> Does that describe Ersek?
>
> A. No. It does not describe Ersek.
>
> Intraluminal delivery is this non-surgical term. It's used in the art for delivery along a body passageway avoiding surgery. Ersek is the antithesis of that. Ersek is a surgical device to use in an open operation to replace the surgeon's sutures, to join something together other than the device it.

Tr. 503:6-17 (emphasis added); *see also* Tr. 505:21-06:5; 507:15-09:14. During his closing argument, Cordis's counsel also compared intraluminal delivery to the surgical *method* of Ersek, instead of comparing the device of claim 23 to the Ersek *device*:

> So what's their case? What's their attack on Dr. Palmaz's work? Ersek. … A device used in open-heart surgery, a device that's completely antithetical to everything that Dr. Palmaz was trying to do. The device was entirely antithetical to his entire profession, to Dotter, Gruntzig and Palmaz.

Tr. 1319:1-7; *see also* Tr. 1319:8-23; 1321:1-10.

Cordis's nonobviousness theory was based on the premise that claim 23 is not a claim to a device but instead is a claim to a device *for use in a particular method*. Dr. Buller testified to this effect during cross-examination:

> Q. Let me just for a moment stay on the device, Dr. Buller. You understand we have a product claim in this case, not a method claim; right?
>
> A. Claim 23 is a product claim, yes, but it's a product *to do a particular thing*.

Tr. 659:8-12 (emphasis added).

Q. Dr. Buller, you're talking about the method of how it got there.

A. No.

Q. You are. You're talking about surgery versus non-surgery and how this got to this place. I'm not talking about that.

I'm talking about the nature of this device and what it's doing right here now. Forget how it got there.

A. Well, it's part of the claim that we're talking about. *Claim 23 is a claim for a device that's intraluminally delivered. This has been intraluminally delivered. This is not a surgical operation.*

Tr. 659:24-60:11 (emphasis added). Cordis's counsel went so far as to demand that Dr. Snyder *assume* that claim 23 covered a device for use in a particular method:

Q. Okay. Let's assume – let's just assume that this is a product claim *for use in a particular process*. Okay?

A. Okay.

Q. It's a product that has the tubular member *for use with intraluminal delivery and controllable delivery*, assume.

A. We want it suitable for that kind of use.

Q. That's what these claim limitations are talking about, okay, *intraluminal delivery to a remote location.*

A. Okay.

Tr. 1018:1-10 (emphasis added).

This premise of Cordis's obviousness theory is incorrect and cannot support the nonobviousness verdict. As explained above, since the body of claim 23 defines a structure and the preamble is not a claim limitation which requires the claimed graft to be used in a particular method, the patentability of the claim "depends on the claimed structure, not on the use or purpose of that structure." *Catalina*, 289 F.3d at 809. Therefore, Cordis's evidence about the differences between noninvasive intraluminal delivery and the invasive surgical method of Ersek is irrelevant and cannot support the verdict.

Cordis also introduced "secondary factors" evidence of nonobviousness—including evidence of long-felt need, skepticism, recognition and praise, and commercial success—but almost all of this evidence also related to the stent-balloon combination and intraluminal method, *not* to the device claimed in claim 23. *See* Tr. 231:20-37:12; 488:6-90:13; 491:3-92:7; 540:4-43:15; 627:3-33:4; 1009:6-15; 1104:13-07:6.[9] None of this evidence about the stent-balloon combination or the intraluminal method was probative of the nonobviousness of the *claimed* invention and therefore cannot support the verdict. *Sjolund*, 847 F.2d at 1582 ("Commercial success is relevant only if it flows from the merits of the *claimed* invention.").

Apart from Cordis's irrelevant evidence that the combination of a stent on a balloon and the method of intraluminally delivering and expanding a stent on a balloon would not have been obvious in view of the surgical method disclosed in the Ersek patent, Cordis did not offer *any* evidence at trial to support the nonobviousness verdict or to challenge BSC's clear and convincing evidence of obviousness. Since there is no legally sufficient evidence to support the nonobviousness verdict, BSC should be granted JMOL of obviousness.

IV. If the Court Does Not Grant BSC JMOL of Invalidity, It Should Grant BSC a New Obviousness Trial.

A. A New Trial Is Warranted Because It Was Prejudicial Error To Preclude BSC's Witnesses From Comparing the Stent-Balloon Combination And Intraluminal Delivery Method of Other '762 Patent Claims to the Device of Claim 23.

The Court should grant BSC a new obviousness trial because it was prejudicial error to permit Cordis to introduce evidence about the stent-balloon combination and intraluminal delivery method covered by other '762 patent claims that were not in suit, while

[9] To the extent that Cordis's objective evidence of nonobviousness did relate to claim 23, it would have been completely undermined by BSC's "Project Olive" evidence that flexibility was far more important to commercial success than the attributes of claim 23. As explained below, it was prejudicial error to exclude this compelling evidence.

simultaneously precluding BSC's witnesses from responding to this evidence by describing and contrasting those other claims with the device claim 23 that was in suit.

As explained above, Cordis's nonobviousness evidence did not compare the device of claim 23 with the Ersek device but instead compared the combination of a stent on a balloon and the noninvasive method of intraluminally delivering and expanding a stent on a balloon with the invasive surgical method disclosed in the Ersek patent. By doing so, Cordis was able to distract the jury from the obviousness of the claimed device with irrelevant and confusing evidence about the nonobviousness of other inventions claimed in other claims of the '762 patent that were not in suit, such as the stent-balloon combination of claim 51 and the intraluminal method of claim 1.

Despite Cordis's confusing and misleading presentation, the Court would not permit BSC's witnesses to respond by explaining the differences between these other inventions and claim 23 in order to focus the jury on the obviousness of the only claim in suit. Tr. 552:10-60:25; 833:21-37:22; 843:16-45:21. This was prejudicial error because there was no basis for excluding this evidence apart from an unsupported concern about jury confusion, when in fact the exclusion of this evidence only increased confusion by impairing the jury's ability to focus on the obviousness of the claim in suit and ignore Cordis's distracting and irrelevant evidence about the nonobviousness of inventions of claims that were not in suit. A new trial is warranted because it cannot be said that it is "highly probable" that the exclusion of this evidence did not affect the obviousness verdict. *See McQueeney*, 779 F.2d at 928.

B. A New Trial Is Warranted Because It Was Prejudicial Error To Preclude BSC From Introducing "Project Olive" Evidence About the Admitted Importance of Flexibility to Commercial Success.

The Court should also grant BSC a new obviousness trial because it was prejudicial error to permit Cordis to assert that the commercial success of all successful stents is

attributable to the structural features of claim 23 while simultaneously precluding BSC from responding with "Project Olive" evidence that Cordis considered flexibility to be far more important to that success.

Despite representing that it would only rely at trial on the commercial success of Cordis's stents as objective evidence of nonobviousness (Tr. 74:12-13), Cordis repeatedly offered evidence and argued to the jury that the commercial success of the entire stent industry—including not only Cordis's stents but also the accused NIR stent and other stents sold by BSC, ACS and AVE—was attributable to the structural features of claim 23. For example, Dr. Buller testified as follows:

> Q. Do you have an opinion as to the relationship between the elements set forth in Claim 23 and successful balloon expandable coronary stents?
>
> A. Yes. I believe that *all of the successful balloon expandable coronary stents* use this unique combination of elements as put forward in Dr. Palmaz's Claim 23 of his '762 patent. They use this combination of elements in the way that Dr. Palmaz taught.

Tr. 704:17-24 (emphasis added).

> Q. Let's take a look at the stents that entered the market in 1997. …
>
> A. … *Here is the Cordis product. Here's the Boston SciMed product. Here's the AVE product, here's the ACS product. They are all using Dr. Palmaz's invention.*

Tr. 706:7-07:17 (emphasis added); *see also* Tr. 108:24-09:3; 118:20-19:8; 172:17-73:21; 189:12-90:2; 191:21-92:4; 200:14-02:3; 321:22-22:9; 327:19-28:15; 401:18-02:8; 487:18-88:5; 531:17-32:3; 704:12-08:6; 838:10-39:10; 842:12-43:14; 1118:2-19:13; 1164:19-22; 1295:18-22; 1308:17-22; 1317:20-18:3; 1329:15-18.

Commercial success is only probative of nonobviousness if the success is due to the claimed invention, not other features which are not claimed. *Sjolund*, 847 F.2d at 1582 ("Commercial success is relevant only if it flows from the merits of the *claimed* invention."). By asserting that the commercial success of all stents is due to the structural features of claim

23, Cordis put the nexus between that success and the claimed invention into issue. BSC was entitled to rebut that alleged nexus. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000).

The Court ruled *in limine* before trial that evidence of "Project Olive" should be excluded (D.I. 1337, ¶ 4(m)) and refused during trial to reconsider that ruling in light of Cordis's evidence about the commercial success of all stents (Tr. 838:10-39:16; D.I. 1364). By excluding this evidence, the Court prevented BSC from rebutting the alleged nexus between commercial success and claim 23 by showing that Cordis itself considered *flexibility*—which is not an attribute of the device claimed in claim 23—to be the most important feature of a commercially successful stent: Shortly after introducing the Palmaz-Schatz stent, Cordis immediately recognized that its lack of flexibility was a significant drawback, that the NIR stent was much more flexible, and therefore that Cordis should spend $335 million—more than three times the $100 million Cordis emphasized to the jury that it invested to bring the Palmaz-Schatz stent to market (Tr. 312:22-13:6; 1292:8-9)—to acquire the NIR stent technology from Medinol. Cordis described the NIR stent as "a very competitive and valuable stent design" because of its "unique flexibility":

> The NIR Stent design is a superior stent design . . . The flexibility aspect of the NIR Stent is a substantial competitive advantage over the current PALMAZ and PALMAZ-SCHATZ Stents and is a feature which can potentially replace up to 50% of our current stent volume …

Memo from Woodall to Dearstyne, dated Sept. 1, 1995 (DX-3168) (attached as Ex. E).

Given the enormous size of the stent market and Cordis's repeated assertions at trial that all of the success of that market was attributable to claim 23, it was very prejudicial to preclude BSC from introducing this compelling evidence about the importance to commercial success that Cordis placed on flexibility, which is *not* an attribute of the device claimed in claim 23. A new trial is warranted because it cannot be said that it is "highly probable" that

the exclusion of this evidence did not affect the obviousness verdict. *See McQueeney*, 779 F.2d at 928.

C. A New Trial Is Warranted Because It Was Prejudicial Error To Permit Cordis to Introduce and Rely On Impeachment Material As Substantive Evidence In Order to Mislead the Jury Into Believing That the Ersek Sleeve Is Like a "Stapler."

The Court should also grant BSC a new obviousness trial because it was prejudicial error to permit Cordis, under the guise of purported impeachment of Dr. Snyder, to introduce and rely on Dr. Ersek's curriculum vitae and Dr. Heuser's testimony to mislead the jury into believing that they had admitted that the Ersek sleeve is like a "stapler" when both of them had actually testified it was not.

One of the critical fact issues at trial was how similar the prior art Ersek sleeve is to the graft described in claim 23. Dr. Buller testified that the Ersek sleeve is completely different from the graft of claim 23 because, even though the Ersek patent does not contain any of these terms, the Ersek sleeve is like a "stapler" with "sharp" edges that "cut" and "penetrate" the tissue wall to provide fixation. *See, e.g.*, Tr. 492:21-500:21; 501:20-04:22; 505:21-10:5; 577:17-80:24; 585:5-87:9; 596:17-98:8. Dr. Snyder testified that the Ersek sleeve does not have sharp edges, does not cut or penetrate the tissue wall, and is not like a "stapler." *See, e.g.*, Tr. 889:24-905:9; 909:10-28:15.

Under the guise of impeaching Dr. Snyder's testimony about the Ersek device, and over BSC's objection (Tr. 1040:22-57:25), the Court permitted Cordis to read to the jury Dr. Ersek's description of the Ersek patent as a "staple-like device" in his curriculum vitae and an excerpt from Dr. Heuser's trial testimony during the recent Cordis-AVE trial which purportedly agreed with Dr. Ersek's description. Tr. 1058:7-60:21; PX-7270 (attached as Ex. F). After representing to the Court that he would "not offer the resume into evidence" (Tr. 1047:24), and after the Court ruled that "this kind of evidence should not be admitted" (Tr.

1044:19-20) because it was only appropriate for impeachment (Tr. 1057:5-20), Cordis's counsel proceeded to refer to Dr. Ersek's description and Dr. Heuser's testimony as substantive evidence during his closing argument. Tr. 1302:1-7; 1320:3-25; 1323:15-24:2.

Dr. Ersek's description of the Ersek patent in his curriculum vitae and Dr. Heuser's testimony about that description had no probative value. As Cordis argued to the Court in its motion *in limine* requesting that the Court bar Dr. Ersek from testifying as an expert witness, "the inventor of a prior art patent should not be permitted to elaborate on the teachings of his own prior art patent." D.I. 1292, Ex. 7 at 10-11. A prior art reference is relevant for what it discloses to a person of ordinary skill in the art at the pertinent time, not what its author had in mind, or meant to say, or thought or did but did not describe in the reference. *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus.*, 145 F.3d 1303, 1312-13 (Fed. Cir. 1998); *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 888 (Fed. Cir. 1984). As the Court ruled in granting Cordis's *in limine* motion, Dr. Ersek is not qualified to give expert testimony about what the Ersek patent would have disclosed to one of ordinary skill in the art and Dr. Ersek's factual knowledge about his device—which includes his description of his patent in his curriculum vitae—is legally irrelevant:

> Dr. Ersek currently is not a qualified expert in the relevant art. To the extent he has factual knowledge about his device, that knowledge is irrelevant unless disclosed in his patent.

D.I. 1329 at 7; *see also* D.I. 1337, Tr. 60-61 ("His patent says what it says, and I don't think it's appropriate for him to be disclosing what he thought his patent said.").

It was very prejudicial to permit Cordis to use this legally irrelevant description in Dr. Ersek's curriculum vitae and the excerpt from Dr. Heuser's testimony as substantive evidence to mislead the jury into believing that both Dr. Ersek and Dr. Heuser disagreed with Dr. Snyder and considered the Ersek device to be like a "stapler." Tr. 1302:1-7; 1320:3-25;

1323:15-21. Although Cordis's counsel repeatedly told the Court otherwise (Tr. 1042:11-13; 1045:14-16; 1051:8-9; 1054:21-25; 1057:5-10), both Dr. Ersek and Dr. Heuser actually testified during the Cordis-AVE trial that they did *not* consider the Ersek device to be like a "stapler." Dr. Ersek testified as follows:

> Q. Did you mean to suggest by calling it a staple-like device that it was a stapler?
>
> A. I never meant to say it was a stapler. It had no staples in it. It doesn't work like a stapler, it works like a slotted tube.

3/9/05 Tr. 1251:7-16 (attached as Ex. G).[10] Dr. Heuser testified as follows:

> Q. … [Y]ou understand that Ersek's device is a staple-like device intended to implant into the vessel wall; right?
> …
>
> A. No, I don't – *I don't agree that it was a staple-like device*.
>
> Q. You don't agree with Dr. Ersek's description of his device?
>
> A. I agree with his description, but *I don't agree that it was a staple-like device*.

3/10/05 Tr. 1601:7-21 (emphasis added) (attached as Ex. H).

By repeatedly telling the jury to consider Dr. Ersek's curriculum vitae and Dr. Heuser's testimony as substantive evidence and by misleading the jury as to the import of that testimony, it is very likely that Cordis confused and misled the jury—in much the same way that Cordis appears to have misled the Court (Tr. 1057:5-10)—into believing that Dr. Ersek and Dr. Heuser considered the Ersek device to be like a "stapler" and that this evidence should be given weight. Indeed, Cordis's counsel argued to the jury that Dr. Ersek's legally irrelevant

[10] Dr. Ersek testified that he only referred to his device as "staple-like" because the device could be used to fasten tissue automatically like a surgical staple, and the device overcame the shortcomings of the McGovern heart valve which used staples as fastening means. Ex. G at Tr. 1250:2-51:6.

description was the best evidence of whether the Ersek patent is like a "stapler":

> Dr. Snyder told you again and again and again. It's not a stapler, doesn't say it's a stapler, says nothing about stapler, says nothing about sharp, says nothing about penetrate. Never, never, never, never.
>
> Well, gee, how to figure if that is true or not. You can read the patent. You can rely on what Dr. Buller told you. *But you could also think, what does Ersek think he invented?* Here's what his resume says about the '744 patent. It's a valve seat, *a new staple-like device* to allow for the rapid installation of prosthetic and transplanted heart valves.

Tr. 1320:3-13 (emphasis added); *see also* Tr. 1323:15-20. Cordis's counsel also exploited this evidence to mislead the jury into believing that Dr. Snyder was the only witness who considered the Ersek device not to be like a "stapler" in order to unfairly isolate him and disparage his credibility, not only with respect to obviousness but also infringement:

> And, lastly, *when you are deciding whether to credit Dr. Snyder's opinion [on infringement]*, an opinion that's contrary to Dr. Low and contrary to Dr. Richter and contrary to Mr. Brown, contrary to Dr. Buller, contrary to all the documents, *when you want to decide when you want to credit Dr. Snyder's opinion, remember, he's the guy who told you Ersek isn't a stapler*.
> …
>
> It's a staple-like device. Who thinks it is? Well, Dr. Buller and Dr. Andros, Dr. Heuser and Dr. Ersek. Who thinks it isn't? Dr. Snyder.
> …
>
> The bottom line, no one has described Ersek as not a stapler except Dr. Snyder. You decide whether to believe him.

Tr. 1302:1-7; 1320:23-25; 1323:23-25. This attack was extremely prejudicial to BSC on both obviousness and infringement, and very likely affected the verdict. BSC should be granted a new trial. *See Ayoub*, 550 F.2d at 170-71.

D. A New Trial Is Warranted Because the Nonobviousness Verdict Is Against the Weight of the Evidence.

Finally, if the Court does not grant JMOL of invalidity, the Court should grant BSC a new obviousness trial because the verdict is against the weight of the evidence, for the reasons set forth in BSC's argument for JMOL of obviousness. *See* Section III *supra*.

CONCLUSION

For the reasons set forth above, BSC respectfully urges the Court to grant BSC's renewed motion for judgment as a matter of law (JMOL) of noninfringement and obviousness, and, in the alternative, for a new trial on infringement and obviousness.

Respectfully submitted,

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